

Exhibit B

Deposition of Richard Dowling December 16, 2009

In Re:

Digitek

Richard Dowling

December 16, 2009

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1 A Between tablets and --

2 Q Okay. Let me give you an example.

3 As I understand it, you press oxycodone into
4 tablets; is that right?

5 A Yes.

6 Q And you press Digitek into tablets;
7 is that right?

8 A Yes.

9 Q My understanding would be that while
10 the blended ingredients are certainly
11 different, the mechanism of pressing it into a
12 tablet, the mechanism of blending, pressing,
13 and then moving it on out of there, those
14 would be essentially the same technologies,
15 wouldn't it?

16 MR. ANDERTON: Objection.

17 You may answer.

18 THE WITNESS: Yes.

19 BY MR. THOMPSON:

20 Q And I've used oxycodone, but if I
21 went down a list of all the solid tablets at
22 the Little Falls plant, the answer would be
23 the same for those as well; isn't that right?

24 MR. ANDERTON: Objection.

1 You may answer.

2 THE WITNESS: Yes.

3 BY MR. THOMPSON:

4 Q How many total presses were there at
5 the Little Falls plant?

6 A I don't remember.

7 MR. THOMPSON: I'm going to
8 come back to this in a minute, but this
9 was on my mind. I wanted to look at this
10 real quickly. This is plaintiff's No.
11 88.

12 (Plaintiff's Exhibit No. 88 was
13 marked for identification.)

14 BY MR. THOMPSON:

15 Q I'll hand you Plaintiff's No. 88,
16 which consists of two pages. I'll take that
17 off for just a second. We'll look at this.
18 Now, are you familiar with redacting? Do you
19 know what that means?

20 A Yes.

21 Q If you look, most of this page has
22 been blacked out. It's been redacted before
23 it was produced. And so that actually makes
24 it easier for us because we just get to just

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1 2005 to 2008, how would you as the director of
2 manufacturing, how would you know to produce
3 Digitek in a certain quantity on a certain
4 day? What would be the work order or what
5 would be the directive that would come to you?

6 A I would receive a weekly production
7 schedule from the production planner.

8 Q Okay. And who was that? Is that a
9 person that's above you or below you?

10 A He was at the VP level so I would
11 say above me.

12 Q Okay. So you would receive a
13 production schedule. And I guess presumably
14 that would reflect the orders that had been
15 received by the company?

16 MR. ANDERTON: Objection.

17 BY MR. THOMPSON:

18 Q If you know.

19 A I don't know. I don't know.

20 Q But in any event, it would come from
21 the production planner. At that point you
22 would take that weekly schedule and what would
23 you do?

24 A It was typically broken down by day

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1 of the week. I would schedule a room,
2 equipment, operators to manufacture the
3 product listed or begin manufacture of the
4 product listed for that particular day.

5 Q And how would you select those
6 operators?

7 A It could vary depending on who was
8 available at the time, but typically the first
9 stage of the process is blending. So I would
10 go to the blending department, which had X
11 number of operators, and see who was available
12 that particular day to start this process on a
13 particular batch.

14 Q So once you made those assignments,
15 would you closely supervise the operators or
16 would you rely on a supervisor or production
17 person to oversee the actual operations?

18 A I would rely on a supervisor or a
19 production person.

20 Q Would there be any occasion where
21 you personally would involve yourself in the
22 routine production operation?

23 A I would monitor the operation.

24 Q When you say "monitor" --

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1 uniformly, that falls within your
2 responsibility, doesn't it?

3 MR. ANDERTON: Objection;
4 mischaracterizes his testimony and this
5 document.

6 THE WITNESS: If there were a
7 need for a manufacturing investigation, I
8 would have been asked by QA to do that.
9 I was not even aware of these results at
10 that time.

11 BY MR. THOMPSON:

12 Q Okay. So as far as you knew during
13 this period, February 20, I guess, '07,
14 through September 29, '07, you were unaware of
15 any blend uniformity problems that may or may
16 not have existed?

17 A I was unaware of these three batches
18 having a blend uniformity problem.

19 Q Well, that's a little bit different.
20 Were you aware of blend uniformity problems
21 among any product that was being produced at
22 the Little Falls plant?

23 MR. ANDERTON: Objection.

24 I instruct the witness to

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1 answer only with respect to Digitek.

2 THE WITNESS: I don't recall.

3 BY MR. THOMPSON:

4 Q All right. Now, this would be a
5 big -- wouldn't this be a big deal if there
6 was a blend uniformity problem? I mean, it
7 would be like written up or something,
8 wouldn't it?

9 MR. ANDERTON: Objection.

10 You may answer.

11 THE WITNESS: There would be an
12 investigation conducted if I was asked to
13 conduct it from the manufacturing
14 perspective, yes.

15 BY MR. THOMPSON:

16 Q If you have a 45-site press, how
17 often does that press cycle? How long does it
18 take for it to punch out 45 pills?

19 A It depends on how the press is set
20 up.

21 Q Say you set it up to run at the
22 regular speed.

23 A That speed would be designated in
24 the batch record, the RPM speed. We would set

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1 reading that.

2 BY MR. THOMPSON:

3 Q Actually, I don't want you to recall
4 reading it. Do you recall the FDA being
5 brought in to I guess stamp or to approve the
6 new production?

7 A Yes, they were called in to approve
8 that facility.

9 Q And instead, after that inspection,
10 you got a series of observations and a series
11 of recalls and then a shuttering of the plant;
12 is that right?

13 MR. ANDERTON: Objection.

14 You may answer.

15 THE WITNESS: We did get
16 observations, yes, during that
17 inspection, yes.

18 (Plaintiff's Exhibit No. 97 was
19 marked for identification.)

20 BY MR. THOMPSON:

21 Q I'll hand you Plaintiff's Exhibit
22 97. Okay. Now, Mr. Dowling, this is an
23 e-mail from you to Bharat Patel and Apurva
24 Patel. It says "new punches Digoxin," dated

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1 December 18, 2007; is that right?

2 A Yes.

3 Q It says: "As part of the corrective
4 action for investigation number 07-093 for
5 Digoxin double tablets, I am going to state
6 that we will buy a complete set of lowers and
7 dies for both strengths of Digoxin that will
8 be dedicated and not used for any other
9 products. It is possible the tablet stuck to
10 the punch and was double compressed.

11 "In addition, we should immediately
12 do the same for the three strengths of --
13 blank or redacted -- right away.

14 "In the long run, the lower punches
15 and dies will last longer if they are
16 dedicated and not used for multiple products,
17 and we won't have to delay set-ups because the
18 lowers or dies needed are in use and not
19 available."

20 Okay? You wrote that; right?

21 A Yes.

22 Q Now, as of December 18, 2007, you
23 did not have a set of lowers and dies that
24 were dedicated solely to use to produce

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1 digoxin; isn't that right?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: We had lower
5 punches and dies as indicated in the
6 production batch record available to use
7 for digoxin.

8 BY MR. THOMPSON:

9 Q Right. But the punches and dies
10 were not reserved solely to use for digoxin,
11 were they?

12 A The lowers and dies were used
13 interchangeably.

14 Q Okay. So when you say
15 "interchangeably," you're saying that the
16 lowers and the dies were used for digoxin and
17 for other products as well; isn't that right?

18 A Yes, they could be used for other
19 products.

20 Q And what other products were they
21 used for?

22 A That I don't recall. They would be
23 products with the same die characteristic or
24 size or the same punch or tablet

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1 configuration.

2 (Plaintiff's Exhibit No. 98 was
3 marked for identification.)

4 BY MR. THOMPSON:

5 Q Keep that one right beside it and
6 let me hand you Plaintiff's Exhibit 98. Did
7 you have a chance to look this over before you
8 came to the deposition today?

9 A Yes, I did.

10 Q Okay. Now, this is an affidavit.
11 And you're aware that an affidavit is a
12 document that's under oath; correct?

13 A Yes.

14 Q And so it's sworn testimony. Now,
15 if I turn to Paragraph 14, read that for me.

16 MR. ANDERTON: I'm sorry. What
17 number?

18 MR. THOMPSON: No. 14.

19 THE WITNESS: "Digitek is
20 produced using what effectively is a
21 custom, Digitek-only tablet press. The
22 base model and make of the tablet press
23 used to manufacture all of the recalled
24 Digitek is a 45 station Stokes BB2 tablet

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1 BY MR. THOMPSON:

2 Q Did you write it?

3 MR. ANDERTON: Objection.

4 I instruct the witness not to
5 answer.

6 BY MR. THOMPSON:

7 Q Did you write the words on this
8 affidavit?

9 MR. ANDERTON: I instruct the
10 witness not to answer.

11 BY MR. THOMPSON:

12 Q Your attorney wrote this affidavit,
13 didn't he?

14 MR. ANDERTON: Objection.

15 I instruct the witness to
16 answer only to the extent you can do so
17 without revealing privileged
18 communication.

19 THE WITNESS: Yes, my attorney
20 assisted with this.

21 BY MR. THOMPSON:

22 Q Now, you knew that this affidavit
23 was going to be used to limit the scope of
24 material in this lawsuit; didn't you know

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1 that?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: I'm not sure I
5 understand the question, "the scope of
6 material."

7 BY MR. THOMPSON:

8 Q You knew that by claiming that the
9 process by which Digitek was produced was
10 unique and used exclusively for the purpose of
11 manufacturing Digitek, that that statement
12 would be used to limit the scope of inquiry in
13 this lawsuit; didn't you know that?

14 A I had an idea that may be what it
15 was for, yes.

16 Q So when you took a statement that a
17 lower punch and die were used to make multiple
18 products and instead wrote the punch and die
19 was used solely and exclusively for the
20 purpose of making Digitek, you knew the
21 purpose for which that statement was going to
22 be used --

23 MR. ANDERTON: Objection.

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1 affidavit.

2 BY MR. THOMPSON:

3 Q Let's look at Paragraph 19. Well,
4 let's go to Paragraph 29. What were the other
5 14 products that were blended in the same room
6 where Digitek was blended?

7 A I don't have independent
8 recollection of all 14 of those products.

9 Q On June 22, 2009, what source did
10 you go to to find out what the other 14
11 products that were blended in the same room as
12 the Digitek blending, what source did you use
13 to make that statement?

14 A I was looking at the approved batch
15 records for those products.

16 Q And those batch records were
17 available to you?

18 A I had to request them from the
19 document control area, yes.

20 Q And was it burdensome and oppressive
21 for you to get those batch records --

22 MR. ANDERTON: Objection.

23 BY MR. THOMPSON:

24 Q -- for the year 2005 through 2008?

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1 MR. ANDERTON: Objection.

2 You may answer.

3 THE WITNESS: No.

4 BY MR. THOMPSON:

5 Q Paragraph 30, what were the ten
6 other products that used the V-shaped blender
7 that was used in the Digitek blending process?

8 MR. ANDERTON: Objection.

9 THE WITNESS: Again, I don't
10 have an independent recollection right
11 now of that.

12 BY MR. THOMPSON:

13 Q And how did you get that
14 information?

15 A I used the same approach. I got the
16 batch record for the other products.

17 Q How long did it take you to get that
18 batch record when you requested it?

19 MR. ANDERTON: Objection.

20 You may answer.

21 THE WITNESS: This process
22 probably took me the good part of two
23 days.

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1 BY MR. THOMPSON:

2 Q And was it burdensome and oppressive
3 for them to fill your request?

4 MR. ANDERTON: Objection.

5 You may answer if you
6 understand.

7 THE WITNESS: I'm not sure what
8 you mean by "burdensome" or "oppressive."

9 But, no, they cooperated with me fully.

10 BY MR. THOMPSON:

11 Q Did it take 12 lawyers and
12 \$4 million to get you the batch records from
13 2005 to 2008?

14 MR. ANDERTON: Objection.

15 THE WITNESS: No.

16 MR. ANDERTON: Mischaracterizes
17 his testimony -- let me finish.

18 THE WITNESS: I'm sorry.

19 MR. ANDERTON: Mischaracterizes
20 his testimony.

21 You may answer.

22 THE WITNESS: No. I worked
23 with a document clerk in the document
24 control room.

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1 BY MR. THOMPSON:

2 Q If somebody represented to a federal
3 court that it would be burdensome and
4 oppressive and very expensive to get the batch
5 records for these products, would that be a
6 truthful statement?

7 MR. ANDERTON: Objection. That
8 is another obvious mischaracterization of
9 any representation that was made to a
10 federal court. And I don't appreciate
11 you formulating questions on the basis of
12 those types of misrepresentations.

13 Now --

14 MR. THOMPSON: Are you
15 directing him not to answer?

16 MR. ANDERTON: I'm not -- I
17 haven't got there yet.

18 If you understand the question,
19 you may answer it.

20 THE WITNESS: I don't believe
21 it was oppressive and burdensome to get
22 this information.

23 BY MR. THOMPSON:

24 Q On Paragraph 34, what were the six

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1 other products that were pressed in either
2 Room 119 or 120 other than Digitek?

3 MR. ANDERTON: Objection.

4 You may answer.

5 THE WITNESS: I don't have
6 independent recollection of those.

7 MR. THOMPSON: Okay. I've got
8 several other people who are dying to ask
9 some questions this afternoon, so I would
10 like to go ahead and pass this witness
11 for a few minutes so that everybody who's
12 come a long way has an opportunity to at
13 least ask some questions. So if that's
14 okay. Thanks very much.

15 THE VIDEOGRAPHER: There's 25
16 minutes left on the tape. Do you want to
17 run it out or change it?

18 MS. SANFORD: Let's change it.

19 THE VIDEOGRAPHER: We are now
20 going off the record. This is the end of
21 Videotape No. 4. The time is 3:30.

22 (Short recess.)

23 THE VIDEOGRAPHER: We are now
24 back on the record. This is the